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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,956	01/29/2001	Michele Bennett Kinrade	U 013223-9	9691

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EXAMINER	
WEGERT, SANDRA L	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/771,956	KINRADE ET AL.	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *91-98* is/are pending in the application.

4a) Of the above claim(s) *91-94* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *95-97* is/are rejected.

7)☒ Claim(s) *98* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 January 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/19/01,8/5/04,8/27/04*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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Detailed Action

Status of Application, Amendments, and/or Claims

The Election, sent 13 December 2004, and the Information Disclosure Statements, sent 5 August 2004 and 27 August 2004, respectively, have been entered into the record. Claims 1-90 are cancelled. Claims 91-98 are new. Applicant traversed the Restriction and argued that the claims of Inventions I and II should be rejoined, since a search of the art for Group I should reveal the relevant art for the other inventive Group. However, the claims of Inventions I and II were restricted properly, because the products of Inventions I and II are independent and distinct, have different putative functions, have different structures, and require completely different search terms, sequence searches, starting points and strategies, and because the measured characteristics of each NPY chimeric receptor are distinct.

Claims 91-94 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Inventions, there being no allowable generic or linking claims.

Claims 95-98 are under examination in the Instant Application.

Claim Objections and/or Rejections

Claim Rejections-35 USC § 112, first paragraph-scope of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 95-97 are rejected under 35 U.S.C. 112, first paragraph, because the Specification, while being enabling for the chimeric NPY receptor of SEQ ID NO: 9, is not enabling for variants of SEQ ID NO: 9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 95-97 are directed to a chimeric NPY receptor in which the C-terminal domain of an NPY5 receptor is replaced by that from an NPY1 receptor. The claims also read on "conservative variants thereof." However, the scope of the patent protection sought by the Applicant as defined by the claims fails to correlate reasonably with the scope of enabling disclosure set forth in the specification for the following reasons:

The specification is not enabling for the full scope of the claims wherein the claims encompass variants of SEQ ID NO: 9, without listing the polypeptides described in the Specification that fall into this genus and function identically to SEQ ID NO: 9. NPY receptors are characterized as having important roles in feeding and cardiovascular functions, among many others (see for example: Wraith, et al, 2000, Genome Res., 10: 302-310 and Blomqvist and Herzog, 1997, Trends Neurosci., 20(7): 294-298). However, the art is primarily unpredictable as far as variants of NPY receptors. In contrast, for example, some receptors, such as the melanocortin receptors, *are* well-characterized in terms of variants and the amino acid residues that must be preserved for normal receptor function (see, for example, Srinivasan, et al, 2004, J. Clin. Invest., 114: 1158-1164). Similarly, there is little data in the current literature concerning replacement of entire domains of NPY receptors. Since Applicants have not made or used any

variants of SEQ ID NO: 9 in their experiments, the claimed NPY5/NPY1 receptor with "conservative variants thereof" is not enabled by the instant Disclosure.

The instant Specification describes measurement of typical characteristics of G-protein-coupled receptors, for the chimeric receptor of SEQ ID NO: 9, such as K_D, B_{max}, and affinities for G_i and G_o (see Figure 1). The NPY chimeric receptor of the claims differs from the NPY5 receptor in each characteristic measured. However, the instant case claims altering the polypeptide of SEQ ID NO: 9 in unpredictable ways. As discussed above, although NPY receptor family members share several common structural features, relevant art (Wraith, et al, 2000, Genome Res., 10: 302-310 and Blomqvist and Herzog, 1997, Trends Neurosci., 20(7): 294-298) shows that members of this class have high homology but do not share a predictable functional attribute or utility, despite having basic structural features in common. Point mutations in similar GPCR's further serve to illustrate this point, since a single amino acid mutation can change the substrate specificity of a receptor or inactivate it (Garabedian and Yamamoto, 1992, Mol. Biol. Cell, 3: 1245-1257-see Fig. 4; Pritchett and Seeburg, 1991, Proc. Natl. Acad. Sci, 88: 1421-1425; and, Kopin, et al, 2003, Proc. Natl. Acad. Sci., 100(9): 5525-5530). These examples and others illustrate that it is not predictable as to which amino acids are necessary to maintain the functional characteristics of most receptor proteins, including those of the instant Disclosure and that undue experimentation would be required to determine a structure-function relationship for each possible polypeptide encompassed by the claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence

or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Due to the large quantity of experimentation necessary to determine an activity or property of the claimed polypeptides such that it can be determined how to use the claimed polypeptides and to screen for activity, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, and the breadth of the claims --undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

35 USC § 112, first paragraph – Written Description.

Claims 95-97 are rejected under 35 USC § 112, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Claims 95-97 are directed to a chimeric NPY receptor in which the C-terminal domain of an NPY5 receptor is replaced by that from an NPY1 receptor. The claims read on "conservative variants thereof" of SEQ ID NO: 9

The specification teaches measurement of art-typical characteristics of the chimeric receptor of SEQ ID NO: 9, such as K_D, B_{max}, and relative affinities for G_i and G_o (see Figure 1). The NPY chimeric receptor of the claims differs from the typical NPY5 receptor in each measured property characteristic. However, the instant claims encompass altering the polypeptide of SEQ ID NO: 9 in unpredictable ways. However, Applicants were not in

possession of variants of SEQ ID NO: 9.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

With the exception of the NPY chimera of SEQ ID NO: 9 referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides, and therefore, would not know how to make or use them. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of making or using. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of use. *The polypeptide itself is required.* See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the polypeptide of SEQ ID NO: 9 meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see

page 1115).

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a recitation of "conservative variants thereof." There is not even identification or discussion of any particular residues that must be conserved (for example, to maintain function). In the absence of a sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Making and using a representative number of variant NPY chimeric receptor proteins is likewise not adequately described.

Claim Objections-

Claim 98 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 95-97 are rejected. Claim 98 is objected to.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The

examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW
3 June 2005

JANET ANDRES
PRIMARY EXAMINER